

Response filed March 22, 2006
Response to Office Action mailed December 22, 2005

Application No. 10/002,328

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A system for establishing therapy parameters of an implantable medical device comprising in combination:

- (a) at least one implantable lead;
- (b) an external neural stimulator capable of being coupled to the implantable lead to provide stimulation energy to the lead in accordance with the initial therapy parameters;
- (c) a programmer having a user interface to allow entry of the therapy parameters by a user, wherein the programmer is configured to provide to the external neural stimulator configuration information for a type of an implantable neural stimulator that is to be implanted; and
- (d) a means for providing a bi-directional communications link between the programmer and the external neural stimulator to enable the programmer to program the external neural simulator with the therapy parameters via the bi-directional communications link and to enable the external neural stimulator to provide final therapy parameter settings to the programmer, whereby the programmer may then program an implantable neural stimulator using the final therapy parameters.

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2. (Currently Amended) A system for establishing therapy parameters of an implantable medical device comprising in combination:

- (a) at least one implantable lead;
- (b) an external neural stimulator capable of being coupled to the implantable lead to provide stimulation energy to the lead in accordance with the initial therapy parameters;
- (c) a programmer having a user interface to allow entry of the therapy parameters by a user, wherein the programmer is further configured to provide to the external neural stimulator configuration information for a type of the implantable neural stimulator that is to be implanted;
- (d) a means for providing a bi-directional communications link between the programmer and the external neural stimulator to enable the programmer to program the external neural simulator with the therapy parameters via the bi-directional communications link and to enable the external neural stimulator to provide final therapy parameter settings to the programmer, whereby the programmer may then program an implantable neural stimulator using the final therapy parameters;
- (e) an implantable neural stimulator capable of being coupled to the implantable lead to provide stimulation energy to the lead; and
- (f) a means for providing a second communications link between the programmer and the implantable neural stimulator to enable the programmer to program the implantable neural simulator with the final therapy parameters via the second communications link.

3. (Cancelled).

4. (Currently Amended) The system as claimed in claim 1, ~~wherein the bi-directional communications link enables~~ the programmer is configured to provide the external neural stimulator with upgraded computer executable instructions.

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5. (Currently Amended) The system as claimed in claim 1, wherein the ~~bi-directional communications link enables the~~ external neural stimulator is configured to provide information to the programmer, wherein the information is selected from the group consisting of parameter settings, patient diagnostic data, system diagnostic data, data on device usage, data regarding the last programmer/ENS session, the state of the device, configuration of the INS 210, and whether a valid communication channel exists.

6. (Original) The system as claimed in claim 5, wherein the parameter setting information is selected from the group consisting of stimulation frequency, stimulation pulse amplitude, stimulation pulse width, and electrode configuration.

7. (Original) The system as claimed in claim 5, wherein the patient diagnostic data is usage data.

8. (Original) The system as claimed in claim 5, wherein the system diagnostic data information is selected from the group consisting of battery status, estimated longevity of implanted device, lead system integrity, and load impedance.

9. (Currently Amended) The system as claimed in claim 1, wherein the ~~bi-directional communications link provides an indication~~ programmer is configured to determine that a viable communications link exists between the programmer and the external neural stimulator.

10. (Original) The system as claimed in claim 1, wherein the programmer is mechanically linked to the external neural stimulator.

11. (Original) The system as claimed in claim 1, wherein the programmer is a physician programmer.

12. (Original) The system as claimed in claim 1, wherein the programmer is a patient programmer.

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13. (Currently Amended) A programmer for establishing therapy parameters of an implantable medical device comprising in combination:

(a) a user interface to allow entry of the therapy parameters by a user;
and

(b) a bi-directional communications interface for communicating with ~~the~~ an external neural stimulator, wherein to enable the programmer is configured to program the external neural simulator with the therapy parameters, the programming including configuration information regarding a type of an implantable neural stimulator that is to be implanted and is further configured to receive final therapy parameter settings from ~~enable the external neural stimulator to provide final therapy parameter settings to the programmer, and wherein whereby the programmer is further configured to may then program the~~ an implantable neural stimulator using the final therapy parameters.

14. (Original) The system as claimed in claim 13, wherein the programmer is a physician programmer.

15. (Original) The system as claimed in claim 13, wherein the programmer is a patient programmer.

16. (Cancelled).

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17. (Currently Amended) A method of establishing initial therapy parameters of an implantable medical device comprising the steps of:

- (a) implanting at least one lead having a distal end, wherein the distal end of the lead is near at a predetermined portion of a body;
- (b) coupling a proximal end of the lead to an external neural stimulator;
- (c) establishing a bi-directional communications link between the external neural stimulator and a programmer;
- (d) ~~programming by the programmer~~ the external neural stimulator with therapy parameters with the programmer, the programming comprising:
 - (i) providing initial therapy parameters to the external neural stimulator; and
 - (ii) providing configuration information for a type of implantable neural stimulator that is to be programmed; and
- (e) providing final therapy parameters to the programmer from the external neural stimulator, whereby the programmer may then program an implantable neural stimulator using the final therapy parameters.

18. (Previously Presented) The method as claimed in claim 17, further comprising the step of:

- (f) adjusting the therapy parameters of the external neural stimulator using the programmer.

19. (Original) The method as claimed in claim 17, wherein the step of programming is performed via telemetry.

20. (Original) The method as claimed in claim 17, wherein the step of programming is performed using a physician programmer.

21. (Original) The method as claimed in claim 17, wherein the step of programming is performed using a patient programmer.

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22. (Currently Amended) A medical system for providing electrical treatment therapy to a patient comprising in combination:

at least one implantable lead delivering treatment therapy to the patient;

an external neural stimulator having a first interface for coupling to the implanted lead for providing stimulation energy to the lead and a first bi-directional communications interface;

an implantable neural stimulator capable of being implanted within a body of a patient and having an second interface for coupling to the implanted lead for providing stimulation energy to the lead and a second bi-directional communications interface;

a physician programmer having a first user interface to allow entry of therapy parameters by a user and a third bi-directional communications interface for communicating with the external and implantable neural stimulators to enable the physician programmer to program the external and implantable neural stimulators with the therapy parameters and to enable the external and implantable neural stimulators to provide therapy parameter settings back to the physician programmer, wherein the physician programmer is further configured to provide to the external neural stimulator configuration information for a type of the implantable neural stimulator that is to be implanted; and

a patient programmer having a second user interface to allow entry of therapy parameters by a user and a fourth bi-directional communications interface for communicating with the external and implantable neural stimulators to enable the patient programmer to program the external and implantable neural stimulators with the therapy parameters and to enable the external and implantable neural stimulators to provide therapy parameter settings back to the patient.

23. (Cancelled).

24. (Currently Amended) The system as claimed in claim 2, ~~wherein the bi-directional communications link enables~~ the programmer is configured to provide the external neural stimulator with upgraded computer executable instructions.

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25. (Currently Amended) The system as claimed in claim 2, wherein the ~~bi-directional communications link enables the~~ external neural stimulator is configured to provide information to the programmer, wherein the information is selected from the group consisting of parameter settings, patient diagnostic data, system diagnostic data, data on device usage, data regarding the last programmer/ENS session, the state of the device, configuration of the INS 210, and whether a valid communication channel exists.

26. (Previously Presented) The system as claimed in claim 25, wherein the parameter setting information is selected from the group consisting of stimulation frequency, stimulation pulse amplitude, stimulation pulse width, and electrode configuration.

27. (Previously Presented) The system as claimed in claim 25, wherein the patient diagnostic data is usage data.

28. (Previously Presented) The system as claimed in claim 25, wherein the system diagnostic data information is selected from the group consisting of battery status, estimated longevity of implanted device, lead system integrity, and load impedance.

29. (Currently Amended) The system as claimed in claim 2, wherein the ~~bi-directional communications link provides~~ programmer is configured to determine whether an indication that a viable communications link exists between the programmer and the external neural stimulator.

30. (Previously Presented) The system as claimed in claim 2, wherein the programmer is mechanically linked to the external neural stimulator.

31. (Previously Presented) The system as claimed in claim 2, wherein the programmer is a physician programmer.

32. (Previously Presented) The system as claimed in claim 2, wherein the programmer is a patient programmer.

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33. (Previously Presented) The medical system as claimed in claim 22, wherein the third bi-directional communications interface enables the physician programmer to provide to the external neural stimulator configuration information for a type of the implantable neural stimulator that is to be implanted.

34. (Previously Presented) The medical system as claimed in claim 22, wherein the third bi-directional communications interface enables the physician programmer to provide the external neural stimulator with upgraded computer executable instructions.

35. (Previously Presented) The medical system as claimed in claim 22, wherein the third bi-directional communications interface enables the physician programmer to provide the implantable neural stimulator with upgraded computer executable instructions.

36. (Previously Presented) The medical system as claimed in claim 22, wherein therapy parameter setting information is selected from the group consisting of stimulation frequency, stimulation pulse amplitude, stimulation pulse width, and electrode configuration.

37. (Previously Presented) The medical system as claimed in claim 22, wherein the third bi-directional communications interface enables the external neural stimulator to provide information to the physician programmer, wherein the information is selected from the group consisting of parameter settings, patient diagnostic data, system diagnostic data, data on device usage, data regarding the last programmer/ENS session, the state of the device, configuration of the INS 210, and whether a valid communication channel exists.

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38. (Previously Presented) The medical system as claimed in claim 22, wherein the third bi-directional communications interface enables the implantable neural stimulator to provide information to the physician programmer, wherein the information is selected from the group consisting of parameter settings, patient diagnostic data, system diagnostic data, data on device usage, data regarding the last programmer/ENS session, the state of the device, configuration of the INS 210, and whether a valid communication channel exists.

39. (New) The method of claim 17, wherein the establishing in (c) comprises:

- (i) establishing a first RF leg of the bi-direction communication link between the programmer and a remote telemetry unit; and
- (ii) establishing a second RF leg of the bi-directional communication link between the remote telemetry unit and the external neural stimulator.